K092845

510(k) Summary

JAN 26 2010

Submitter's Name / Address: NOMICS s.a.

Liege Science Park
Rue des Chasseurs Ardennais, 4
4031 - Angleur
BELGIUM

Tel: + 32 (0) 4 372 93 48
Fax: + 32 (0) 4 372 93 12

Contact Person: Pierre Ansay (CEO)

Date Prepared: January 14th, 2010

Device Trade or Proprietary Name: RESPISENS

Common or Usual Name: RESPISENS

Classification Name: Accelerator, Linear, Medical
CFR 892.5050
Class II
Product Code – IYE

Predicate Devices: RPM Respiratory Gating system (K983629)
RPM Respiratory Gating system (K063270)
Active Breathing Coordinator – ABC system (K003330)

Device Description:

The Respisens system monitors patient motion in real time during radiotherapy. The system is based on a transmitter/receiver that measures distance. When placed on the patient's thorax or abdomen, the system tracks breathing and thus helps monitoring and securing breath hold manoeuvres. If placed on a motionless part of the patient, it helps verify immobility. The underlying technology is a magnetic distance sensor that is capable of measuring movements with high sensitivity.

The Respisens system is composed of a Respisens measurement module and an Interface Box, their accessories, and a user interface software. The Respisens measurement module drives the sensor. The Interface Box is the control core of the system. It sits in the control room and handles the communication with the PC, the calculation of the time lag in signal display introduced by the PC, the detection of the status of the radiation beam, and the alarms.

Intended Use:

The Respisens system is intended to monitor patient motion in real time during radiotherapy. In particular, the system is intended to monitor breath hold and to detect undesirable patient motion. Monitoring respiratory motion during breath hold is essential in ensuring patient safety. The system warns the operator when breath hold is not maintained properly. Verifying that the patient stays completely still during treatment is also fundamental. The system can detect patient movement and warn the operator when necessary.

Both the Respisens system and the RPM Respiratory Gating system (K983629 and K063270) display and record patient respiratory motion during radiation therapy procedures and can be used to monitor the patient position. However, the new device does not start and stop the radiation beam in synchrony with the respiratory waveform (= gating) and therefore its indications for use are a subset of those of the RPM Respiratory Gating system. By comparison, the Respisens system and the ABC system (K003330), which also displays and records patient respiratory motion during radiation therapy procedures (but can not be used to monitor patient position), are alike in that they both are stand alone and independent of the therapy system and therefore do not offer the gating feature.

Technological Characteristics and Nonclinical Testing:

The layout and the technological characteristics of the new device are similar to those of the predicate devices. The Respisens system has been the subject of nonclinical testing to demonstrate that the differences, in particular in sensing technologies, do not adversely affect the safety or effectiveness of the device. Performance data have been submitted to show that the device achieves its intended use and performs comparably to predicate devices. Design, labeling, biocompatibility, electromagnetic compatibility, and electrical safety have been verified to comply with applicable requirements. Software verification and validation was also performed.

Summary of Substantial Equivalence:

The Respisens system is similar in intended use, layout, and performance characteristics to the predicate devices. The differences that exist between the devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Pierre Ansay
Managing Director
Nomics S.A.
WSL Liège Science Parc, Rue des Chasseurs Ardennais, 4
B-4031 Angleur
BELGIUM

JAN 26 2010

Re: K092845
Trade/Device Name: RESPISENS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 15, 2010
Received: January 19, 2010

Dear Mr. Ansay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092845

Device Name: RESPISENS

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K092845